

**Remarks/Arguments:**

By this amendment, claims 1, 8, 10, 13, 29-39, 41-42, 44-53, 55-63 are amended, and claims 1-63 are pending.

**Restriction Requirement**

The Office Action imposed a restriction requirement under 35 U.S.C. § 121 between an anti-reflux valve prosthesis, a tool for insertion of the valve, and a method of using the tool. Group I, claims 1-34, and 56 are directed the anti-reflux valve; group II, claims 29-35, 38, 41, 44-52, 55, 57, and 60-63 are drawn to the tool for implantation of the anti-reflux valve; and group III, claims 36-37, 39-40, 42-43, 53-54, and 58-59 are drawn to the method of using the tool. Applicant provisionally elects the invention of Group I, drawn to claims 1-34 and 56, with traverse.

The Office Action stated that the inventions of Group I and Group II are related as subcombinations usable together in a single combination. The examiner has stated that the subcombinations are distinct from each other if they are shown to be separately usable. MPEP 806.05(d). The Office Action stated that invention I has separate utility as a heart valve that can be implanted by hand in an open heart procedure. However, as claimed, the valve of claim 1 is designed to be placed in the esophagus to inhibit the retrograde passage of gastric juices. See for example, claim 13.

Furthermore, restriction is only proper when the claims are directed to independent and distinct inventions. See MPEP 806.05. The MPEP states, "[t]he term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect." MPEP 802.01. Claims 29-35, 38, 41, 44-52, 55, 57, and 60-63, as amended, are written in dependent form and

specifically depend from the anti-reflux valve prosthesis of claim 13. Thus, the claims drawn to the tool are not independent, and as drafted, specifically require the valve prosthesis of claim 13. Therefore, it is improper to restrict the dependent claims drawn to the tool, and withdrawal of the restriction requirement is respectfully requested.

Similarly, method claims 36-37, 39-40, 42-43, 53-54, and 58-59, as amended, are drafted in dependent form and are therefore not distinct and independent. Restriction between method and apparatus claims is only proper if it is shown that either (a) the process as claimed can be practiced by another materially different apparatus or by hand, or (b) that the apparatus as claimed can be used to practice another materially different process. See MPEP 806.05(e). The claims drawn to the method specifically depend from and cannot be practiced without the anti-reflux valve prosthesis of claim 13. Thus, the claims drawn to the method are not independent, and as drafted, specifically require the valve prosthesis of claim 13. It is therefore improper to restrict the claims drawn to the method, and withdrawal of the restriction requirement is respectfully requested.

Furthermore, if the invention of either Group II or Group III is examined, no additional burden is placed on the examiner to examine the other because each comes from the same class and subclass. See MPEP 803.

#### Species Election

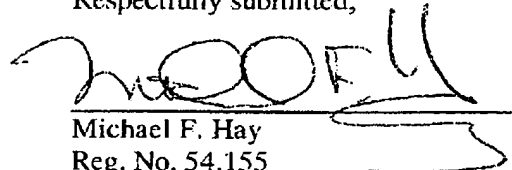
The Office Action also required the election of species under 35 U.S.C. § 121, requiring the applicant to select a single disclosed species for the annular body species from Figure 1 or Figure 17A, and a single disclosed species for the valve species from either Figure 1 (element 12) or Figure 14. The applicant hereby provisionally elects the species of the annular body of Figure 1 and the valve species of Figure 1, with traverse. Applicant believes independent claim 1, 10, and

13, and claims 2-9, 11-12, 14-63 depending from claims 1, 10, and 13, are readable on the elected species. Applicant traverses the election requirement in that it is believed claim 13 is generic for the elected species and is allowable. If generic claim 13 is allowed, all claims which include the limitations of the generic species should be allowed. See MPEP 806.04(d).

Applicant respectfully requests further examination of the application and upon allowance of a generic claim with respect to the elected species, examination of all claims with respect to the non-elected species as well. Allowance of all claims is respectfully requested.

Applicant does not believe any fees are due at this time, however the Commissioner is authorized to charge any fees associated with this communication to deposit account 501285. If the Examiner has any questions or comments regarding this communication, the undersigned can be contacted to expedite the resolution of this application.

Respectfully submitted,



Michael F. Hay  
Reg. No. 54,155  
Lundeen & Dickinson, L.L.P.  
PO Box 131144  
Houston, Texas 77219-1144  
(713) 652-2555  
(713) 652-2556 Fax  
ATTORNEY-FOR-APPLICANT